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10/091,878	03/05/2002	Terry G. Kelley	COCH-0010	6957

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EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/01/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/091,878

Applicant(s)

KELLEY, TERRY G.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2 & 6.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 20 August 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Three of the cited references (10, 32 and 33) are noted as being voluminous and easily obtainable by the Examiner. The Examiner does not have access to these references and they have not been considered. It is suggested that copies of only the relevant portions of these documents be submitted for consideration. It is noted that listed documents 32 and 33 appear to be the same reference.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

In line 3, after "material" is the limitation "patch body," which is inconsistent from the prior use of "patch or mask body." Appropriate correction is required.

### ***Claim Rejections***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

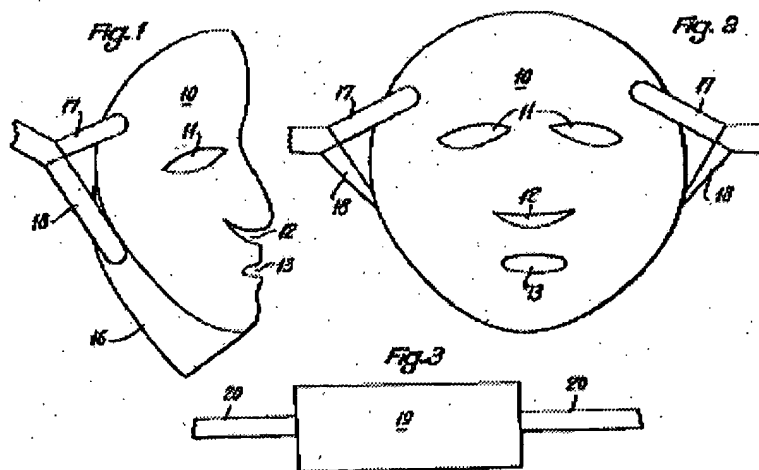
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 16, 17, 22, 25, 26, 31 and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Meckelburg (US 3,154,070).

Regarding claim 1, Meckelburg teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

a flexible patch or mask body (10, 19) formed of a porous material (col. 2, lines 8-21), said patch body (10, 19) sized and dimensioned to conform to a facial or neck skin area of said subject;

attachment means (17, 18, 20) connected to the patch or mask body (10, 19) for securely, removably attaching the patch or mask (10, 19) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (col. 1, lines 21-25; col. 4, lines 19-23) provided in chemical communication with an undersurface of the patch or mask body (10, 19) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask is applied (see figures 1-3, below)(col. 1, lines 21-25; col. 4, lines 19-40).



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Regarding claim 2, Meckelberg teaches a facial or neck patch or mask wherein the flexible patch or mask body (10, 19) is sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject selected from an orbital margin, nasal skin area, labial margin, mandibular, maxillary, or temporal lateral facial skin area, chin, jaw and/or neck skin area of the subject (see figures 1-3).

Regarding claim 3, Meckelberg teaches a facial or neck patch or mask wherein the facial or neck patch or mask conforms and stretches in conjunction with normal facial and neck skin movements as occur during jaw flexure, head turning, and eye opening and closure (col. 2, lines 17-40, discusses elastic construction of the device).

Regarding claim 4, Meckelberg teaches a patch or mask body (10, 19) constructed for expansion and/or elastic flexure in all directions planar to an undersurface of the patch or mask that is applied to a facial or neck skin area to be treated (col. 2, lines 17-40).

Regarding claim 5, Meckelberg teaches attachment means (17, 18, 20) selected from: a tie, elastic or other manual closure means that attaches to opposing lateral margins of the patch or mask (10, 19) and encircles a head of the subject.

Regarding claim 6, Meckelberg teaches a facial or neck patch comprising an orbital patch or mask (10, 11) sized and dimensioned to conform to an orbital margin of the subject for treatment of periorbital skin aging in the subject (see figures 1 & 2).

Regarding claim 7, Meckelberg teaches a orbital patch or mask (10) which conforms (11) to one or more portions of the orbital margin of the subject selected from a supraorbital margin, infraorbital margin, lateral orbital and/or medial orbital margin of the eye (see figures 1 & 2).

Regarding claim 8, Meckelberg teaches a patch or mask (10) comprising one or more separate or conjoined, countoured sections (11) individually shaped and dimensioned to conform to a selected portion of the orbital margin (see figures 1 & 2).

Regarding claim 9, Meckelberg teaches a orbital patch or mask (10) wherein said one or more separate or conjoined, countoured sections (11) are individually shaped and dimensioned to conform to a portion of the orbital margin selected from: a lenticular area of the supraorbital margin; a lenticular area of the infraorbital margin; a medial orbital margin; and a lateral orbital margin (see figures 1 & 2).

Regarding claim 10, Meckelberg teaches one or more separate or conjoined, countoured sections (11) are conjoined in a single patch or mask (10) having a unitary body or by interconnecting member(s) joining the individual sections in an anatomically integrated array of sections (see figures 1 & 2).

Regarding claim 11, Meckelberg teaches a facial or neck patch or mask (10) comprising a nasal skin patch or mask sized and dimensioned to conform (12) to a nasal skin surface of the subject for treatment or prevention of nasal skin aging in the subject (see figures 1 & 2).

Regarding claim 12, Meckelberg teaches a facial or neck patch or mask (10) comprising a labial skin patch or mask sized and dimensioned to conform (12) to a labial margin of the subject for treatment or prevention of perilabial skin aging in the subject (see figures 1 & 2).

Regarding claim 13, Meckelberg teaches a facial or neck patch or mask (19) comprising a neck skin patch or mask sized and dimensioned to conform to a neck skin surface of the subject for treatment or prevention of neck skin aging in the subject (see figure 3).

Regarding claim 16, Meckelberg teaches the facial or neck patch or mask (10, 19) wherein the patch or mask body, or at least an undersurface portion thereof, serves as a substrate or reservoir for receiving and retaining the anti-aging effective compound (col. 2, lines 17-40).

Regarding claim 17, Meckelberg teaches a the facial or neck patch or mask (10, 19) wherein the anti-aging effective compound is absorbed, adsorbed, or otherwise admixed with or invested in a material of the patch or mask body in direct chemical communication between the patch or mask body and the undersurface thereof through pores, fissures, perforations, and/or other communication channels provided within the patch or mask body (10, 19) or a layer thereof adjacent the undersurface (col. 2, lines 17-40).

Regarding claim 22, Meckelberg teaches a plurality of anti-aging effective compounds are applied simultaneously or coordinately with the patch or mask to yield enhanced treatment or prophylaxis of skin aging in the subject (col. 3, lines 19-23).

Regarding claim 25, Meckelberg teaches a facial or neck patch or mask (10, 19) comprising a facial mask (10) shaped and dimensioned to conform to multiple facial skin areas (see figures 1 & 2).

Regarding claim 26, Meckelberg teaches a facial mask further comprising a separate or integral, self-contained or externally charged thermal element (column 1, lines 57-60).

Regarding claim 31, Meckelberg teaches a patch or mask body (10, 19) comprised of a polymer or fiber material (col. 2, lines 7-40).

Regarding claim 32, Meckelberg teaches a method for treating facial and/or neck skin aging in a mammalian subject comprising: applying a facial or neck patch or mask (10, 19) to a

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facial and/or neck skin area(s) in the subject, wherein the patch or mask comprises a flexible patch body formed of a porous material sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject; and removably securing the patch or mask (10, 19) to the facial and/or neck skin area(s) by attachment means (17, 18, 20) connected to the patch body (10, 19), wherein the patch or mask (10, 19) delivers an anti-aging effective compound to the facial skin and/or neck skin area(s) from an undersurface of the patch or mask body after the patch or mask has been applied to yield enhanced delivery and bioavailability of the anti-aging compound to underlying facial and/or neck skin area(s) to substantially prevent or alleviate one or more symptoms of facial and/or neck skin aging therein (claim 1).

Claims 1 and 27-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by De St. Cyr (US 2,210,618).

Regarding claim 1, De St. Cyr teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

a flexible patch or mask body (1) formed of a porous material (11), said patch body (1) sized and dimensioned to conform to a facial or neck skin area of said subject;

attachment means (10) connected to the patch or mask body (1) for securely, removably attaching the patch or mask (1) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (heated paraffin wax) provided in chemical communication with an undersurface of the patch or mask body (1) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask (1) is applied (see Fig. 1, below).

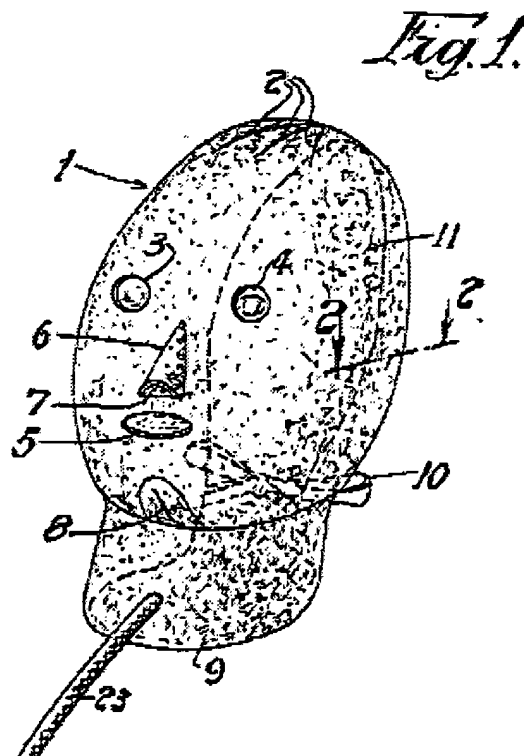


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Regarding claim 27, De St. Cyr teaches a facial or neck patch or mask (1) wherein the thermal element is a heating element (col. 2, lines 29-44) to facilitate delivery and activity of the anti-aging effective compound by increasing the temperature at a target skin area.

Regarding claim 28, De St. Cyr teaches a facial or neck patch or mask wherein the thermal element is a thermal gel (melted wax) that can function as a heating and/or cooling element.

Regarding claim 29, De St. Cyr teaches a facial or neck patch or mask of claim wherein the thermal element is permanently or removably enclosed within a pocket or cavity attached to or surrounded by the patch or mask body (col. 2, lines 29-44).



Regarding claim 30, De St. Cyr teaches a facial or neck patch or mask of wherein the anti-aging effective compound (wax) is formulated with a polymeric delivery vehicle, hydrogel, or biodegradable polymer or matrix.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Korol (US 4,747,845).

Meckelberg expressly teaches the claimed invention except for delayed release of the compound.

Korol teaches a synthetic resin matrix for extended release of medicaments which can be applied via an external skin dressing (abstract, figure 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the drug release mechanism of Korol to the mask or patch of Meckelberg in order to provide a means of controlling the release rate of its active compounds.

Regarding claim 15, Meckelberg teaches a facial or neck patch or mask of claim wherein the patch or mask effectively delivers the anti aging effective compound to achieve an effective concentration anti aging effective compound to reduce or prevent symptoms of facial and/or neck skin aging caused by degeneration of the microvascular system (col. 2, lines 38-40).

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Regarding claim 24, any time released compound provided by the combination of Meckelberg and Korol would provide controlled, time-release delivery of one or more compound(s) for a prolonged delivery time period selected from: 1-4 hours; 4-8 hours; or more than 8 hours.

Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Lorenz (US 5,306,504 A).

Meckelberg teaches the claimed invention except for a bioadhesive.

Lorenz teaches a skin adhesive hydrogel (abstract).

At the time of the invention, it would have been obvious to combine the skin adhesive of Lorenz with the mask or patch of Meckelberg in order to provide a means of better securing the mask or patch to a patient while minimizing skin irritation.

Claims 20, 21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Kaddurah-Daouk (US 6,242,491 B1).

Meckelberg teaches the claimed invention except for the specific anti-aging compound.

Kaddurah-Daouk teaches the use of Coenzyme Q<sub>10</sub> or vitamin E as an anti-aging agent (col. 15, lines 7-11).

At the time of the invention, it would have been obvious to select Coenzyme Q<sub>10</sub> or vitamin E as the anti aging agent for the mask or patch of Meckelberg in order to provide a effective skin preserving effect.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, John Calvert may be reached at phone number (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 746-3380 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.



Michael Bogart  
20 February 2004



JOHN D. CALVERT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700